DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Exactech, Incorporated
% Ms. Meredith L. May, MS, RAC
Empirical Consulting, LLC
4628 Northpark Drive
Colorado Springs, Colorado 80918

August 15, 2014

Re: K141129
Trade/Device Name: Exactech Cervical Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: July 14, 2014
Received: July 18, 2014

Dear Ms. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K141129

Device Name
Exactech Cervical Spacer System

Indications for Use *(Describe)*

The Exactech Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one disc level from C2-T1. Degenerative Disc Disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Exactech Cervical Spacer System is to be used with autogenous bone graft and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

Type of Use (Select one or both, as applicable)
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(K) SUMMARY

Submitter's Name:	Exactech
Submitter's Address:	2320 NW 66th Court Gainesville, Florida 32653
Submitter's Telephone:	(352) 377-1140
Contact Person:	Meredith L. May MS, RAC Empirical Testing Corp. 719.337.7579
Date Summary was Prepared:	30 April 2014
Trade or Proprietary Name:	Exactech Cervical Spacer System
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Cervical
Classification:	Class II per 21 CFR §888.3080
Product Code:	ODP
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

Cervical Spacer System implants are anterior cervical interbody devices consisting of a PEEK (polyetheretherkeytone) implant cage with tantalum radiographic markers.

The Cervical Spacer System is intended for use as an interbody fusion device and offered in a variety of heights, footprints, and lordotic angles to accommodate varying anatomical conditions. The devices features a chamber intended to be filled with autogenous bone graft material.

INDICATIONS FOR USE

The Exactech Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one disc level from C2-T1. Degenerative Disc Disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Exactech Cervical Spacer System is to be used with autogenous bone graft and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

The indications for use for the Cervical Spacer System is similar to that of the predicate devices.

TECHNOLOGICAL CHARACTERISTICS

The Exactech Cervical Spacer System is an anterior cervical interbody composed of the PEEK Optima® LT1 trapezoidal shaped implant with tantalum radiographic markers that is similar to many devices cleared for sale in the United States, including the referenced predicate devices. It is intended for use as an interbody fusion device and is offered in a variety of heights, footprints, and lordotic angles to accommodate varying anatomical conditions. The device features an

enclosed chamber intended to be filled with autogenous bone graft material. The implants are intended for single use only.

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism

Table 5-1 Predicate Devices

510(k) Number	**Trade or Proprietary or Model Name**	**Manufacturer**
K121649	CONSTRUX™ MINI Spacer System	Orthofix Spinal
K090064	Copperhead System	Eminent Spine
K120486	AVS AS System	Stryker Spine
K130317, K103034	Apache™ Interbody Fusion System Star Cervical PEEK	Genesys Spine
K121103, K113559, K091088	Spine MC+ Cervical Cage	LDR
K130948	Cervical IBFD	Southern Spine

PERFORMANCE DATA

The Cervical Spacer System has been tested in the following test modes:

- Static axial compression per ASTM F2077-11
- Static torsion per ASTM F2077-11
- Static Subsidence per ASTM F2267-04
- Static Expulsion per ASTM F-04.25.02.02 (draft)
- Dynamic axial compression bending fatigue per ASTM F2077-11
- Dynamic Torsion per ASTM F2077-11

The results of this non-clinical testing show that the strength of the Cervical Spacer System is sufficient for its intended use and is substantially equivalent to the legally marketed predicate devices, for which there may be no publically available published performance data.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Cervical Spacer System is substantially equivalent to the predicate devices.